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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,180	02/13/2002	Robert J. Hariri	009516-0050-999	9742

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,180	HARIRI, ROBERT J.	
	Examin r	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *19-53 and 55-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-59 are pending, however, claims 19-53, and 55-59 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claims 1-18 and 54 are under current examination.

Claim Objections

Claim 11 is objected because of claim recitation, "OCT-4" and "ABC-p". The abbreviation should be spelled out the first time it appears in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite because of the claim recitation, "OCT-4-" is inconsistent with the specification. The specification teaches that the embryonic-like stem cells are "OCT-4 positive" (Specification, page 21, line 24), yet the claim recites that the stem cells in the perfused placenta are OCT-4 negative, it is unclear whether applicants intend to claim a placenta containing the OCT-4 negative embryonic-like stem cells and whether such stem cells exist, thus, the metes and bounds of the claims could not be readily determined.

Claim 11 is vague and indefinite because of the claim recitation, "ABC-p+". The specification fails to define the term, a quick search of the abbreviation in the PubMed database would find the term is not well recognized in the art, it stands for "antibodies bound/cell", "antibody-binding capacity", as well as "Placenta ABC protein", and thus, the metes and bounds of the claims could not be readily determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by *Sanders* (US 3,862,002), and as evidenced by *Larsson et al* (Angiogenesis 2002;5:107-10) and *Kurtzberg et al* (New Eng J Med 1996;335:157-66).

Claims are drawn to an isolated mammalian placenta which has been recovered after birth, exsanguinated, and perfused under sterile conditions, wherein the solution used to perfuse the placenta contains an anticoagulant, antimicrobial solution, or growth factors, wherein the placenta is from human, has been stored for 2 to 24 hrs after the expulsion from the uterus, and has been perfused or incubated for a period from 2 hrs to more than 48 hrs.

Sanders teaches a human placenta which has been recovered after birth, exsanguinated, incubated in a sterile medium containing anticoagulant and disinfectant such as broad spectrum antibiotic (column 2, lines 45-62), wherein the incubation are performed preferably within 6 hrs of delivery (column 3, lines 1-3). *Sanders* teaches exsanguinating and perfusing the placenta in a culture flask apparatus (figures 1-3) under sterile conditions (column 4, lines 56-67). The perfusion solution taught by *Sanders* contains growth factors because first, the perfusion solution contains human blood plasma (column 5, lines 7-8), which comprising growth factors as evidenced by *Larsson et al;* and second, the placenta would secrete growth factors such as chorionic gonadotropin (column 7, lines 9-61) to the perfusion solution. *Sanders* also teaches that the incubation and perfusion period could last for days since there is a 3-5 day lag for reestablishing the metabolic activity and proliferation of placenta cells after preparation trauma. Claim 7 recites, ""under conditions to allow for the production of embryonic-like stem cells and other multipotent stem cells from said placenta", here the condition is not specified. However, since it is known that the placenta contains hematopoietic stem

cells under normal physiological condition as evidenced by *Kurtzberg et al*, the placenta taught by *Sanders* meets claim limitation. Therefore, *Sanders* anticipates instant claims.

Claims 1-5, 7-10, 12-14, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by *Muhlemann et al* (Placenta 1995;16:367-73).

Muhlemann et al teach a human placenta which has been recovered after birth, exsanguinated, incubated in a sterile medium containing anticoagulant (heparin) and antibiotics (page 368), wherein the incubation and perfusion was performed by a 2hr control period followed by up to 9.5 hrs experimental period (total 11.5 hrs, table 1). The perfusion solution contains growth factors such as chorionic gonadotropin and human placenta lactogen (table 1). The placenta taught by *Muhlemann et al* was maintained under normal physiological condition, thus meet claim limitation for production of embryonic-like stem cells. Therefore, *Muhlemann et al* anticipate instant claims.

Claim 54 is rejected under 35 U.S.C. 102(b) as being anticipated by *Ordi et al* (Am J Surg Pathol 1998;8:1006-11).

Claim 54 is drawn to an isolated placenta containing any cell, which is neither fetal nor maternal in origin.

Ordi et al disclose isolated human placentas containing malaria parasite cells (abstract), which is neither fetal nor maternal in origin. Thus, *Ordi et al* anticipate the instant claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/074,976.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application and that of the cited patent application are each drawn to an isolated mammalian placenta which has been expelled from the body of the mammalian, exsanguinated and perfused with perfusion solution for collecting embryonic-like stem cells from said placenta.

The processes of the present application and the cited patent application differ one from the other in the claim language, however, considerable overlap in the scope of the claims is noted. Therefore, the claims of the present and cited patent applications are obvious variants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Clark can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
August 25, 2003